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June 6, 2005

BY FAX AND MAIL

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
Post Office Box 4010
Sacramento, California 95812-4010

Re: Comments on Workshop on Potential Regulatory Action Exempting from the Proposition 65 Warning Requirements Exposures from Chemicals that Form from Natural Constituents in Food during Cooking or Heat Processing

Dear Ms. Oshita:

I am writing on behalf of Frito-Lay, Inc., to expand on the views presented on its behalf at the May 9, 2005 workshop.

Frito-Lay applauds the recognition by OEHHA that the recent discovery of the chemical acrylamide in cooked foods calls for special review of regulatory options under California's Proposition 65 that will effectuate the purpose of the statute and result in sound public policy. Frito-Lay appreciates the opportunity to provide OEHHA with its views on the conceptual regulatory approach that OEHHA is considering.

I. An Exemption Will Further the Purposes of Proposition 65.

In the course of the May 9 workshop, OEHHA staff asked the participants to address the question of whether OEHHA has the authority to adopt the "conceptual regulation" that was presented for purposes of discussion. Frito-Lay believes such an exemption is consistent with the intentions of the voters who approved Proposition 65 and with prior case law interpreting the current "naturally occurring" exemption. We therefore believe that OEHHA not only has the authority, but also the responsibility, in order to effectuate the purposes of Proposition 65, to adopt a clear regulation exempting unintended byproducts of cooking from the Proposition 65 warning requirements.

The touchstone for analyzing the intent of the voters and the purposes of Proposition 65 on this issue is the California Court of Appeal's decision in *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652 (1991). That ruling endorsed OEHHA's authority to

define the term "expose" to exclude naturally occurring chemicals in food in the regulation at section 12501, volume 22, California Code of Regulations. Its analysis was based on both the language of Proposition 65 and the purpose of the statute. The same analysis of the "conceptual" regulation presented by OEHHA shows that it too would be consistent with Proposition 65 (and that, if presented with the question, a reviewing court would uphold OEHHA's authority to enact such a regulation).

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A. The Language of Proposition 65 Supports an Exemption.

As the *Nicolle-Wagner* court noted, "[t]he controlling language of the Proposition . . . provides that 'no person in the course of doing business shall *knowingly and intentionally expose* any individual . . . ,' thereby suggesting that some degree of *culpable* human activity which results in toxins being added to the environment is required." *Id.* at 659 (first emphasis in original; second emphasis added).

Acrylamide is not *intentionally* added to any food products. Acrylamide adds no flavor, no texture, and no nutritional content to food. Far from being an intended component, its presence was, until recently, completely unknown to anyone – including the best food scientists and chemists in the world. Acrylamide is clearly an *un*intended and indeed an unwanted byproduct of the cooking process.

Likewise, there is nothing "culpable" about the universal human activity of cooking food. Indeed, cooking is an essential part of the production of safe and healthy food, as are such currently exempted human activities as "sowing, planting, irrigation, or plowing." 22 Cal. Code Regs. § 12501(a)(3).

It therefore is consistent with the language of the statute for OEHHA to exempt unintended byproducts of cooking from the scope of the law.

B. The Purpose of Proposition 65 Supports an Exemption.

In upholding the "naturally occurring" exemption in its current form, the *Nicolle-Wagner* court found that the regulation reasonably effectuates the purpose of Proposition 65. The court reached that conclusion based on the following factors:

- "[M]ost food products contain at least trace amounts of [listed] carcinogens and reproductive toxins."
- There is a "paucity of scientific data regarding the risks posed by exposure to such naturally occurring substances."
- "We all presume, to some extent, that foods that have been eaten for thousands of years are healthful, despite the presence of small amounts of naturally occurring toxins."

- "[T]he rationale for this special treatment of foodstuffs is . . . to recognize the general safety of unprocessed foods as a matter of consumer experience."

- "Were these substances not exempted from [the] warning requirements, the manufacturer or seller of such products would bear the burden of proving" that they pose no significant risk, but "such evidence largely does not exist. Thus, grocers and others would be required . . . to post a warning label on most, if not all, food products."

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- "Since one of the principal purposes of [Proposition 65] is to provide 'clear and reasonable warning' of exposure to carcinogens and reproductive toxins, such warnings would be *diluted to the point of meaninglessness* if they were to be found on most or all food products."

Id. at 660-61 (emphasis added). Because every one of these factors is also present with respect to unintended byproducts of cooking, an exemption for such chemicals would further the purposes of Proposition 65.

II. An Exemption Will Not Reduce Incentives for Acrylamide Reduction.

At the May 9 workshop, comments were presented expressing concern that an exemption would diminish technical efforts by food companies to reduce the formation of acrylamide in cooked foods. That concern is not well-founded.

First, technical personnel from Frito-Lay, together with food scientists around the world, are working intensively on better understanding the process of acrylamide formation and ways to reduce it while continuing to provide healthful and appetizing food products. That effort was initiated not by any regulatory action but by the mere announcement by Swedish researchers that acrylamide is present in most food products. Regardless of whether regulators require it to do so, Frito-Lay, among other food companies, is committed to providing safe and healthful products to the public.

Second, Frito-Lay, like most large food companies, operates in a global environment in which the actions, statements, and interests of regulatory agencies around the world affect its products. The U.S. Food & Drug Administration has been intensively reviewing the acrylamide issue, as have counterpart agencies in other countries, particularly in Europe. Frito-Lay is sharing data with these regulators, participating in international consortiums, and otherwise working on ways to reduce acrylamide formation in foods. These regulators, who are vested with very broad authority, are insisting on responsible approaches to this issue, and will continue to do so regardless of what OEHHA does on this issue.

Third, viewed from a different perspective, requiring Proposition 65 warnings for acrylamide formed during cooking will provide little incentive to reduce the levels of acrylamide in food products that are highest in acrylamide. As other information recently released by OEHHA shows, the levels of acrylamide in many food products are one to

two orders of magnitude higher than both the current "safe harbor" level of 0.2 micrograms/day and the proposed "safe harbor" level of 1.0 micrograms/day. Although there are methods of moderately reducing acrylamide levels in some such foods, there is no known way to reduce acrylamide to a level even near the 1.0 microgram/day level, and particularly not while maintaining the appetizing and healthful attributes of these foods. As a result, for many food products, the current Proposition 65 regulatory structure provides little incentive to reduce acrylamide levels, since there is no practical prospect of being able to achieve the level required to avoid a Proposition 65 warning.

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III. The Proposed Exemption Should Be Clear and Practical.

Finally, Frito-Lay believes it is critical, as a matter of good policy, for OEHHA's proposed regulation to be clear, unambiguous, and easy to apply in practice. Food makers like Frito-Lay need to know what is necessary in order to comply with the law. A regulation that is unclear, or open to interpretation or argument, will only lead to litigation over its meaning, with attendant expense, delay, and uncertainty. All of this can be avoided with a clear and unambiguous statement in the regulations that chemicals created during cooking are not regulated by Proposition 65.

For example, the conceptual regulation suggested by the workshop notice uses the terms "lowest level currently feasible" and "good cooking . . . processes," neither of which has any precise meaning that a manager could rely on in producing a compliant product. It is unclear how OEHHA would interpret these terms, or even what a judge would do to determine what they mean. Nevertheless, Frito-Lay remains confident that more precise and unambiguous language can be developed in the regulatory process once OEHHA proceeds beyond the "conceptual" regulation presented at the May 9 workshop for purposes of discussion.

IV. OEHHA Should Proceed to Propose a Regulatory Exemption.

Again, Frito-Lay encourages OEHHA to proceed with proposing regulatory language that will further the purposes of Proposition 65 by exempting the unintended byproducts of cooking. We appreciate the opportunity to provide these comments and look forward to participating in the regulatory process on this issue.

Sincerely,

Trent Norris /JB

Trenton H. Norris